



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/731,231	12/07/00	GUEGLER	K CL001007

025748
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HM12/1106

EXAMINER	
FRONDA, C	
ART UNIT	PAPER NUMBER

1652

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/731,231

Applicant(s)

Guegler et al.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 8, 9, and 24-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 4, 8, 9, 24, and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. In the **PRELIMINARY AMENDMENT** dated October 24, 2001 (Paper No. 11), Applicants have canceled claims 1-3, 5-7, 10-23; amended claims 4 and 8; and added new claims 24-29.

Election/Restriction

2. Applicant's election of Group III in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 4, 8, 9, and 24-29 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4, 8, 9, 24, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all possible polynucleotides encoding a protein comprising SEQ ID NO:2. The specification, however, only provides a single representative species encompassed by these claims: a polynucleotide consisting of a nucleotide sequence of SEQ ID NO:1 which encodes a human kinase. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. There is no written description of the amino acid sequence that is N-terminal or C-terminal of the amino acid sequence of SEQ ID NO: 2. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties other than a polynucleotide consisting of a nucleotide sequence of SEQ ID NO:1 which encodes a human

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kinase for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 8, 9, 24, and 27-29 which depend from claim 4 are also rejected because they do not correct the defect of claim 4.

6. Claims 4, 8, 9, 24, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a human kinase comprising the amino acid sequence of SEQ ID NO:2 or an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO: 3, does not reasonably provide enablement for any isolated polynucleotide encoding any polypeptide comprising the amino acid sequence of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompasses any isolated polynucleotide encoding any polypeptide comprising the amino acid sequence of SEQ ID NO:2. The specification provides guidance and examples for making an isolated polynucleotide encoding a human kinase comprising the amino acid sequence of SEQ ID NO:2 or an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO: 3. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of any polynucleotide encoding any polypeptide comprising the amino acid sequence of SEQ ID NO:2 is lacking. Thus, searching for the biological function, biological activity, or utility of said polynucleotide is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said polynucleotides is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said polynucleotide is enormous. Such experimentation entails screening a vast number of organisms for an organism containing said polynucleotide, isolating the polynucleotide from the selected organism, and determining the biological function, biological activity, or utility of the polynucleotide. Since routine experimentation in the art does not

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include screening for vast numbers of polynucleotides which encode a polypeptide comprising the amino acid sequence of SEQ ID NO:2, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function relationship of the claimed polynucleotides. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 8, 9, 24, and 27-29 which depend from claim 4 are also rejected because they do not correct the defect of claim 4.

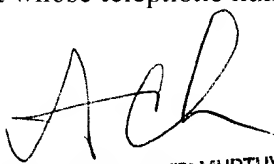
Conclusion

7. Claims 25 and 26 are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Robinson teaches an isolated nucleic acid encoding a human kinase (see entire patent)

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF


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